

ILSI RISK SCIENCE INSTITUTE

International Life Sciences Institute

October 12, 2001

Henry Anderson, M.D.
Chairman
Policies and Procedures Subcommittee
Executive Committee
EPA Science Advisory Board
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Dear Dr. Anderson:

Thank you for the opportunity to provide comment and suggestions on this most important EPA Science Advisory Board activity directed at assuring scientific integrity, accountability and transparency in the work in which the Board engages on behalf of the Agency. Credible peer review of technical products which address key scientific issues is a cornerstone to their success in contributing to wise regulatory decision-making.

My comments/suggestions are based upon a re-read of the GAO report and a review of 1) the Table of Responses that SAB staff prepared as a plan of response to the Report; 2) the Guidelines for Service on the SAB; 3) the Privacy Act; 4) the Federal Advisory Committee Act; 5) the SF-450 Financial Disclosure Report; 6) the NRC policy; 7) the Agency's Peer Review Handbook-2nd Edition; and 8) selected FDA documents on requests for nominations for committees and the portions of transcripts of meetings in which public disclosure of participants' interests, expertise, etc. was made as well as reflections on my own experience with oversight responsibilities for the FIFRA Scientific Advisory Panel and EDSTAC.

In addition, I am providing a copy of the Policies and Procedures for the ILSI Risk Science Institute's (ILSI RSI) Model Peer Review Center of Excellence. As is described in the document, the Model was developed at the request of EPA's Office of Solid Waste and Emergency Response (OSWER) under the terms of a cooperative agreement between OSWER and ILSI RSI. A Conflicts of Interest and Bias Questionnaire has been developed for prospective peer reviewers. It is both simpler (with respect to financial sources) and more thorough (with respect to potential for bias) than is the SF 450. The first four questions would be answered to a great extent by successful completion of the SF 450. The biggest problem I see with the SF 450 is that it asks only about the past year. I believe that it would be much more informative and helpful if the information were available for a longer historical time frame. We have chosen four years. The answers to the remaining questions provide written documentation of information

which would better allow characterization of potential for bias. The key here is that this documentation is written and provided before the decision is made to extend an invitation, not simply discussed in some telephone or face-to-face conversation between the candidate peer reviewer and the manager of the peer review or at the public meeting, itself. Thus, my first recommendation: Get it **all** in writing—well ahead of time.

I also have attached a file of the literature that the ILSI RSI Steering Committee for the Peer Review Center project reviewed when developing the Policies and Procedures. It may be of some value in the development of new approaches for SAB activities. More recently, as you undoubtedly know, controversy has arisen, and is being addressed, with respect to scientific research funded by pharmaceutical firms and published in several key medical journals. Discussions and decisions related to this controversy described recently in the scientific and popular press may also be of value in your subcommittee's deliberations (e.g., Davidoff, et al. (2001) Sponsorship, authorship, and accountability. JAMA 286 (10): 1232-1234 (September 12) and the announcement by the International Committee of Medical Journal Editors of revised requirements submitted to biomedical journals (<http://biz.yahoo.com/prnews/010910/hsm027.htm>)).

With respect to the five questions posed in your request letter, here are some thoughts.

1) What specific types of information about SAB panel members would be useful to you as you assess a panel for possible conflicts of interest and bias? Please provide specific, concrete suggestions if possible.

As “outsiders,” members of the public are not privy to the specifics documented in the SF 450. However, I would strongly recommend that on the first day of each public event, each Panel member/consultant summarize in a sentence or two their financial circumstances. I believe that this can be done, while still being sensitive to the provisions of the Privacy Act. Also, each Panel member/consultant should summarize their written answers to any additional enquiries on a written questionnaire that cover the non-financial conflict and bias topics (e.g., as illustrated in the ILSI RSI Policy and Procedures document and the NRC policy). In addition, the DFO should announce any waivers that have been granted and the basis for the decision(s). Then, all of this information should become an Appendix to all Meetings' minutes and/or (sub)Committees' reports, along with the documentation for the granting of any waivers.

2) What information would be useful for you to know about EPA's panel selection decision-making process? That is, what do you need to know to determine if we've done an acceptable review of conflict of interest and bias and if we've adequately balanced a panel?

One measure by which acceptability could be judged would be sufficient revelation of information by each Panel member in the public meeting, with that information documented in the written products (as noted above in #1) so that any reader/listener would easily understand the decision logic for assembling that particular Panel. While it cannot be guaranteed that everyone listening to or reading the “revelations” will always reach the same conclusions about thoroughness and balance that EPA did, at least they will know how EPA got there. And,

again, it would be documented in writing in the minutes or report of the (sub)committee.

3) What is your reaction to the enclosed table of proposed procedural changes that SAB staff has developed? Please bring to our attention to concerns about the specifics in this table as well as additional concerns or recommendations that merit our attention.

The problem with tables is that they can provide only a very brief description of content and intention. Therefore, it is difficult to determine if the actions proposed will be adequate to satisfactorily address the issues at hand. For example, I do not take issue with the fact that SAB DFO staff should be trained to identify “particular matters” and then make determinations as to whether projects are “particular matters,” and documenting that decision. But, I am just as interested—perhaps, more so—in how robust the training is, how often it is given, and if/how the documentation will be communicated to the world at large, etc. And, so it goes with the other proposed “solutions.” They all look well-intentioned, but “The devil is in the details.”

Some specific comments:

SAB Response A.b. Where will documentation be recorded?

SAB Response B.1.a. The fact that a review of a SF450 has occurred should be documented in writing, i.e. Name of reviewer, name of Panel member, date reviewed, date approved by Deputy Ethics official.

SAB Response B.2.a. I have not seen the modified SF 450s that FDA and NIH use, but I have looked at the NRC policy. There are some important areas covered by the NRC policy that should be incorporated into EPA’s practices: 1) Organizational affiliations (this transcends the usual simpler financial links); 2) Research support; 3) Government service-past and present participation on other advisory boards/committees; 4) Public statements/positions. I see this latter area being covered on a topic-by-topic basis. That is, when individuals are being identified to serve on a standing committee, they would not have to provide this information at that time. But then, when a meeting(s) is/are scheduled to address a specific topic, all standing members and any *ad hoc* members who are named to participate in meetings on that topic must provide *written* documentation on public statements/positions well in advance of the meeting, so that SAB staff have sufficient time to determine if any conflicts exist and whether the panel is balanced. The “survivors” of this vetting process must then declare this information in the public forum. And, lastly, I think EPA should develop a policy and procedures for dealing with scientific misconduct. NRC demands notification if and when a committee member becomes the subject of an investigation. EPA should do so, also.

SAB Response B.2.B. The questions currently included in the Agency’s Peer Review Handbook regarding conflict/bias are not adequate. They must be supplemented with others, such as are included in the NRC policy.

SAB Response C.3. It’s one thing to propose to do ethics training on an annual basis for standing members of a committee. What is proposed for training the *ad hoc* members that are named for one topic/one meeting?

SAB Response E.1.a. I don't understand this statement. What does the Agency have in mind here? What information the public thinks it "needs" may not be able to be shared with them, by virtue of the provisions of the Privacy Act.

4) What other areas should concern the Policies and Procedures Subcommittee beyond the specific areas identified by the GAO report and/or this table? For example, to achieve our broad aim of ensuring continued integrity and accountability of board advice, should we be looking beyond committee composition to other aspects of committee operations? Should we reconsider how we recruit potential panel members, including the development of lists of qualified scientists? We would appreciate any specific recommendations on how we should proceed in each area of concern to you.

EPA should continue to use a variety of procedures for identifying potential panel members, including the Federal Register, the SAB website, and, perhaps, through professional societies/organizations' communication links.

5) Are there other model advisory committees for us to research or scholarly papers that have been written on these issues that might inform the deliberations of the committee?

See discussions above on ILSI RSI Model Peer Review Center of Excellence and the NRC policy on disclosure.

I hope these comments are useful. If you have any questions, please do not hesitate to contact me.

Sincerely,
/s/

Penelope A. Fenner-Crisp, Ph.D., DABT
Executive Director
ILSI Risk Science Institute
One Thomas Circle, Ninth Floor, N.W.
Washington, DC 20005-5802
Telephone: 202-659-3306
Fax: 202-659-3617
Email: pfennercrisp@ilsi.org

Enclosures